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IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

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XLEAR, INC., a Utah corporation,

Plaintiff,

v.

STS HEALTH, LLC, a Virginia Limited  
Liability Company,

Defendant.

**MEMORANDUM DECISION  
AND ORDER DENYING  
MOTION TO DISMISS**

Case No. 2:14-cv-00806-DN

District Judge David Nuffer

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Defendant STS Health, LLC (“STS”) filed a motion to dismiss (“Motion”)<sup>1</sup> Xlear, Inc.’s (“Xlear”) First Amended Complaint (“Complaint”).<sup>2</sup> STS argues that the asserted patent claims of U.S. Patent No. 6,054,143 (“‘143 Patent”) are invalid under [35 U.S.C. §§ 101](#), 102(e), and 112. Xlear disagrees and opposes the Motion.<sup>3</sup> For the reasons stated below, the Motion is DENIED.

**RULE 12(B)(6) MOTION TO DISMISS STANDARD OF REVIEW**

When considering a motion to dismiss for failure to state a claim, the thrust of all well-pleaded facts in the complaint is presumed.<sup>4</sup> The complaint’s legal conclusions and opinions are not accepted, whether or not they are couched as facts.<sup>5</sup> A pleading that offers ‘labels and

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<sup>1</sup> Defendant STS Health, LLC’s Motion to Dismiss Plaintiff Xlear, Inc.’s First Amended Complaint under [Fed. R. Civ. P. 12\(b\)\(6\)](#) and Memorandum in Support (“Motion”), [docket no. 29](#), filed April 13, 2015.

<sup>2</sup> First Amended Complaint (“Complaint”), [docket no. 28](#), filed March 23, 2015.

<sup>3</sup> Plaintiff’s Memorandum in Opposition to Defendant’s Motion to Dismiss the First Amended Complaint under [Fed. R. Civ. P. 12\(b\)\(6\)](#) (“Opposition”), [docket no. 31](#), filed May 26, 2015.

<sup>4</sup> See *Cory v. Allstate Ins.*, 583 F.3d 1240, 1244 (10th Cir. 2009).

<sup>5</sup> See *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). See also *Brown v. Zavaras*, 63 F.3d 967, 972 (10<sup>th</sup> Cir. 1995).

conclusions’ or ‘a formulaic recitation of the elements of a cause of action will not do.’”<sup>6</sup>

“Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.”<sup>7</sup> “[N]aked assertions devoid of further factual enhancement,”<sup>8</sup> do not state a claim sufficiently to survive a motion to dismiss.

“[T]he mere metaphysical possibility that *some* plaintiff could prove *some* set of facts in support of the pleaded claims is insufficient; the complaint must give the court reason to believe that *this* plaintiff has a reasonable likelihood of mustering factual support for *these* claims.”<sup>9</sup>

That is, “[t]he allegations must be enough that, if assumed to be true, the plaintiff plausibly (not just speculatively) has a claim for relief.”<sup>10</sup> “This requirement of plausibility serves not only to weed out claims that do not (in the absence of additional allegations) have a reasonable prospect of success, but also to inform the defendants of the actual grounds of the claim against them.”<sup>11</sup>

### FACTUAL ALLEGATIONS

The Complaint makes the following factual allegations, which are presumed true for purposes of a motion to dismiss:<sup>12</sup>

1. U.S. Patent No. 6,054,143 (“the ‘143 Patent”) relates generally to a method of nasal administration of xylitol. The ‘143 Patent was issued on April 25, 2000 bearing the title “Xylitol Delivery.”<sup>13</sup>

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<sup>6</sup> *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 555).

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> *The Ridge at Red Hawk, LLC v. Schneider*, 493 F.3d 1174, 1177 (10th Cir. 2007).

<sup>10</sup> *Robbins v. Oklahoma* 519 F.3d 1242, 1247-48 (10th Cir. 2008).

<sup>11</sup> *Id.* at 1248.

<sup>12</sup> *Cory*, 583 at 1244 (instructing that when considering a motion to dismiss for failure to state a claim, the court presumes the thrust of all well-pleaded facts in the complaint, but need not consider conclusory allegations).

<sup>13</sup> Complaint ¶ 5.

2. Dr. Alonzo H. Jones (“Dr. Jones”), the named inventor of the technologies claimed in the ‘143 Patent, began his research on the effects of xylitol in response to his granddaughter’s frequently recurring earaches.<sup>14</sup>

3. Dr. Jones, who was an independent family physician practicing in Hale Center, Texas, studied the research pointing to the anti-bacterial affects [sic] of xylitol in the prevention of tooth decay. Dr. Jones also recognized that many infection-causing bacteria enter through the nose, and that chronic inadequate nasal hygiene accounts for most upper respiratory infections including Otitis media (middle ear infections), asthma, sinusitis and allergies.<sup>15</sup>

4. Applying the information obtained in his research in a novel way, Dr. Jones experimented on the effects and benefits of nasal sprays containing xylitol.<sup>16</sup>

5. Through his experimentation Dr. Jones discovered that xylitol administered through the nose did have a beneficial and/or preventative effect on a variety of upper respiratory bacterial infections.<sup>17</sup>

6. A provisional patent application related to this discovery (application no. 60/079184 (“184 App.”)) was filed with the U.S. Patent and Trademark Office (“USPTO”) on March 24, 1998. U.S. Patent Application No. 09/220,283 (“283 App.”) was subsequently filed claiming priority to the provisional application.<sup>18</sup>

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<sup>14</sup> *Id.* ¶ 6.

<sup>15</sup> *Id.* ¶ 7.

<sup>16</sup> *Id.* ¶ 8.

<sup>17</sup> *Id.* ¶ 9.

<sup>18</sup> *Id.* ¶ 10.

7. The USPTO examined the ‘283 App. and did not reject the claims that issued from that application based on 35 U.S.C. § 101. The ‘283 App. issued as the ‘143 Patent.<sup>19</sup>

8. The ‘184 App. discloses, among other things, a preparation prepared by mixing xylitol with a saline solution that is effective for reducing the incidence of upper respiratory infection in those at risk for recurrent infections and includes a beneficial washing effect.<sup>20</sup>

9. Due to the long felt need for Dr. Jones’s invention, sales of Xlear nasal washes and sprays incorporating the patented technology were and continue to be substantial.<sup>21</sup>

10. Xlear has at all times relevant hereto marked its xylitol nasal washes and sprays with the patent number for the ‘143 Patent.<sup>22</sup>

11. Xlear has recently become aware that Defendant is selling or offering to sell nasal sprays containing xylitol through its website <http://www.stshealth.com/flunada/>.<sup>23</sup>

12. Defendant’s nasal sprays instruct and actively induce users to nasally administer an effective amount of xylitol/xylose in solution, and therefore infringe either literally, equivalently or contributorily one or more claims in the ‘143 Patent.<sup>24</sup>

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<sup>19</sup> *Id.* ¶ 11.

<sup>20</sup> *Id.* ¶ 12.

<sup>21</sup> *Id.* ¶ 13.

<sup>22</sup> *Id.* ¶ 14.

<sup>23</sup> *Id.* ¶ 15.

<sup>24</sup> *Id.* ¶ 16.

13. Defendant's website, <http://www.stshealth.com>, provides instruction on the method users of its products should follow to nasally administer an effective amount of xylitol/xylose to the nasopharynx of a human.<sup>25</sup>

14. Xlear is the assignee of all right, title and interest in the '143 Patent.<sup>26</sup>

15. The '143 Patent has not expired and is in full force and effect.<sup>27</sup>

### **JUDICIAL NOTICE**

Under Federal Rule of Evidence 201, "[t]he court may judicially notice a fact that is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned."<sup>28</sup> STS asks the court to take judicial notice of the following:

1. Entire patent prosecution history of U.S. Application Serial No. 09/220,283 (now U.S. Patent No. 6,054,143 (Ex. A));

2. Entire patent prosecution history of U.S. Application Serial No. 09/517,929 (now U.S. Patent No. 6,258,372 (Ex. B));

3. Entire patent prosecution history of U.S. Application Serial No. 09/429,255 (now U.S. Patent No. 6,599,883 (Ex. C));

4. U.S. Provisional Patent Application No. 60/079,184 (Ex. D);

5. U.S. Provisional Patent Application No. 60/106,388 (Ex. E);

6. Xylitol characteristics as set forth in the above patent documents; and

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<sup>25</sup> *Id.* ¶ 17.

<sup>26</sup> *Id.* ¶ 18.

<sup>27</sup> *Id.* ¶ 19.

<sup>28</sup> [Fed. R. Evid. 201](#).

7. Alonzo H. Jones, *Intranasal Xylitol, Recurrent Otitis Media, and Asthma: Report of Three Cases*, 2 Clinical Prac. Alternative Med. 112 (2001) (Ex. F).<sup>29</sup>

STS argues that the court may take judicial notice of these things because they are public records whose accuracy cannot be reasonably disputed.<sup>30</sup>

Xlear “does not challenge the *authenticity* of the USPTO documents (exhibits A-E to the Motion [items 1-5 above]),”<sup>31</sup> but argues that “the Court should not take judicial notice of *exhibits B, C, and E* because those documents are *irrelevant*.”<sup>32</sup>

In the context of patents, district courts may “take judicial notice of patent documents such as the patent’s prosecution history.”<sup>33</sup> Relevance is not a consideration when determining whether to take judicial notice. Instead, under Rule 201, a court “may judicially notice a fact that is *not subject to reasonable dispute . . .*”<sup>34</sup> Here, Xlear does not dispute the authenticity of exhibits A through E. Therefore, judicial notice is taken of items 1-5 (exhibits A-E), above.

Xlear also challenges the taking of judicial notice of “[x]ylitol characteristics as set forth” in the exhibits. Xlear argues that STS “does not specifically identify what those characteristics are,” which is problematic according to Xlear because without identifying “the specific facts of which it wants the Court to take judicial notice[,] . . . neither Xlear nor the Court knows what

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<sup>29</sup> Defendant’s Second Request for the Court to Take Judicial Notice of Certain Documents from the United States Patent and Trademark Office and Other Public Records (“Request for Judicial Notice”) at 4-5, [docket no. 30](#), filed April 13, 2015.

<sup>30</sup> *Id.* at 4 (citing [Fed. R. Evid. 201\(b\)](#)).

<sup>31</sup> Plaintiff’s Memorandum in Opposition to Defendant’s Second Request to Take Judicial Notice of Certain Documents from the United States Patent and Trademark Office and Other Public Records (“Opposition to Request for Judicial Notice”) at 2, [docket no. 32](#), filed May 26, 2015 (emphasis added).

<sup>32</sup> *Id.* at 3 (emphasis added).

<sup>33</sup> *Won-Door Corp. v. Cornell Iron Works, Inc.*, No. 2:13-cv-00331, 2014 WL 119320 at \*2 (D. Utah Jan. 13, 2014) (unpublished).

<sup>34</sup> [Fed. R. Evid. 201\(b\)](#) (emphasis added).

facts have been judicially noticed.”<sup>35</sup> Xlear is correct. Judicial notice of a fact may be taken, but Xlear has not identified a specific statement, fact, or characteristic regarding xylitol that it would like the court to take judicial notice of. Instead, Xlear broadly asks for judicial notice of “[x]ylitol characteristics as set forth in the above patent documents.”<sup>36</sup> Accordingly, judicial notice is *not* taken of “xylitol characteristics as set forth in the above patent documents.”

Finally, Xlear challenges the taking of judicial notice of the article by Alonzo H. Jones.<sup>37</sup> Xlear argues that “it is inappropriate for the court to take judicial notice of facts on a webpage whose source and reliability are unknown.”<sup>38</sup> Xlear also argues that “[t]here is nothing to indicate that Dr. Jones has anything to do with the website or that the website should be treated as authenticating the article at issue, nor has Defendant explained the relevancy of the article or the judicial fact that should be noticed.”<sup>39</sup> Xlear is correct. This article is not “generally known” within the jurisdiction of this court and the article’s authenticity cannot be accurately and readily determined from sources whose accuracy cannot reasonably be questioned. The article has not been cited in Xlear’s Complaint and it is not central to the Complaint. Therefore, judicial notice is not taken with respect to the article.

Items 1-5 in the above list are judicially noticed. Items 6 and 7 are *not* judicially noticed.

## DISCUSSION

STS advances four arguments in support of its Motion. First, STS argues that the ‘143 Patent is invalid under [35 U.S.C. § 101](#) because it is directed to patent-ineligible subject matter.<sup>40</sup>

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<sup>35</sup> Opposition to Request for Judicial Notice at 3.

<sup>36</sup> Request for Judicial Notice at 5.

<sup>37</sup> Opposition to Request for Judicial Notice at 3.

<sup>38</sup> *Id.*

<sup>39</sup> *Id.*

<sup>40</sup> Motion at 4-13.

Second, STS argues that the ‘143 Patent is invalid under 35 U.S.C. § 112 ¶ 1, and cannot be infringed.<sup>41</sup> Third, STS argues that the ‘143 Patent is invalid under 35 U.S.C. § 112 ¶ 2.<sup>42</sup> Fourth, STS argues that the ‘143 Patent is invalid as being anticipated under 35 U.S.C. § 102(e).<sup>43</sup> Each argument will be addressed in turn.

### **STS Does Not Establish that the ‘143 Patent Is Invalid under 35 U.S.C. § 101**

First, STS argues that the ‘143 Patent is invalid under 35 U.S.C. § 101 because it is directed to patent-ineligible subject matter.<sup>44</sup> STS is incorrect.

A two-step framework “distinguish[es] patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts.”<sup>45</sup> The first step is to “determine whether the claims at issue are directed to one of those patent-ineligible concepts.”<sup>46</sup> If so, the next step is to determine if there are “additional elements [to] transform the nature of the claim into a patent-eligible application.”<sup>47</sup> A valid patent must be “significantly more than a patent upon the [ineligible concept] itself.”<sup>48</sup>

#### **Step 1 – The ‘143 Patent Is Not Directed to A Patent-Ineligible Concept**

Claim 1 is the only independent claim of the ‘143 Patent. It provides:

1. A method of cleaning the nasopharynx in a human in need of said method which comprises nasally administering an effective amount of xylitol/xylose in solution.<sup>49</sup>

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<sup>41</sup> *Id.* at 13-15.

<sup>42</sup> *Id.* at 15-19.

<sup>43</sup> *Id.* at 19-21.

<sup>44</sup> *Id.* at 4.

<sup>45</sup> *Alice Corp Pty Ltd. v. CLS Bank International*, 134 S.Ct. 2347, 2355 (2014).

<sup>46</sup> *Id.*

<sup>47</sup> *Id.*

<sup>48</sup> *Id.* (alteration in original).

<sup>49</sup> ‘143 Patent, col. 4:55-57 (Claim 1).



STS argues this claim is patent-ineligible subject matter under § 101 because “[x]ylitol is a natural compound, a derivative of xylose, obtained especially from birch bark, and has long been used as a sweetener.”<sup>50</sup> STS also argues that “[x]ylose is found in the body . . . .”<sup>51</sup> Therefore, according to STS, the ‘143 Patent fails at Step 1 because it simply recites a law of nature, which is not patentable.<sup>52</sup>

Xlear disagrees, and contends that STS “incorrectly asserts that the ‘143 Patent is directed towards natural phenomena.”<sup>53</sup> Instead, Xlear argues, the ‘143 Patent “does not claim as an invention the discovery of xylitol/xylose and the exclusive right to every application of xylitol/xylose.”<sup>54</sup> Rather, Xlear contends, Claim 1 is for a process or “method” of cleaning the nasopharynx in a human using xylitol/xylose.<sup>55</sup> The plain language of Claim 1 supports Xlear’s position, claiming “[a] *method* of cleaning the nasopharynx . . . .”<sup>56</sup>

The USPTO’s Interim Guidance also supports Xlear’s position with an example of a patent-eligible claim:<sup>57</sup>

A method of treating breast or colon cancer, comprising: administering an effective amount of purified amazonic acid to a patient suffering from breast or colon cancer

The USPTO explains this claim is patent-eligible because:

Although the claim recites a nature-based product (amazonic acid), analysis of the claim as a whole indicates that the claim is *focused on a process* of practically applying the product to treat a particular disease (breast or colon cancer), and not

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<sup>50</sup> Motion at 6.

<sup>51</sup> *Id.*

<sup>52</sup> *Id.* at 6-7.

<sup>53</sup> Opposition at 6.

<sup>54</sup> *Id.*

<sup>55</sup> *Id.*

<sup>56</sup> ‘143 Patent, col. 4:55-57 (Claim 1) (emphasis added).

<sup>57</sup> Opposition at 6-7 (citing USPTO 2014 Interim Guidance on Patent Subject Matter Eligibility (December 16, 2014), available at [http://www.uspto.gov/patents/law/exam/mdc\\_examples\\_nature-based\\_products.pdf](http://www.uspto.gov/patents/law/exam/mdc_examples_nature-based_products.pdf)).

on the product *per se*. Thus, it is not necessary to apply the markedly different characteristics analysis in order to conclude that the claim is not directed to an exception . . . . The claim qualifies as eligible subject matter.<sup>58</sup>

Xlear argues the same analysis should apply here. Xlear is correct that although Claim 1 of the ‘143 Patent recites a nature-based product (xylitol/xylose), the claim as a whole is *focused on the process* of practically applying the product to treat a particular condition (cleaning the nasopharynx).<sup>59</sup> Therefore, Xlear is correct that the ‘143 Patent “claims *methods for the delivery* of xylitol/xylose, not the naturally occurring product itself.”<sup>60</sup> However, Xlear is incorrect that the inquiry ends there. The Interim Guidance does not discuss whether a process or method (not just the product) has additional features that transform it into a patent-eligible application. If the product is a law of nature and the process or method described in the patent is not novel or claims nothing more than the law of nature, the claim is not patent-eligible.<sup>61</sup> That analysis will be conducted below.

## Step 2 – “Additional Features” Test

The Supreme Court has long held that a patent is not automatically valid simply because it claims a process or method.<sup>62</sup> Rather, the process or method must have “additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself.”<sup>63</sup> Patents cannot “simply recite a law of nature and then add the instruction ‘apply the law.’”<sup>64</sup> The Supreme Court has suggested that

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<sup>58</sup> Opposition at 7 (quoting Interim Guidance) (emphasis added).

<sup>59</sup> Opposition at 7-8.

<sup>60</sup> *Id.* at 6 (emphasis added).

<sup>61</sup> See *Mayo Collaborative Svcs. v. Prometheus Labs.*, 132 S.Ct. 1289, 1298-1300 (2012).

<sup>62</sup> See *id.* (explaining different outcomes in *Diamond v. Diehr*, 450 U.S. 175 (1981) and *Parker v. Flook*, 437 U.S. 584 (1978), both of which involved method patents).

<sup>63</sup> *Mayo*, 132 S.Ct. at 1297.

<sup>64</sup> *Id.*

Einstein, we assume, could not have patented his famous law by claiming a process consisting of simply telling linear accelerator operators to refer to the law to determine how much energy an amount of mass has produced . . . . Nor could Archimedes have secured a patent for his famous principle of flotation by claiming a process consisting of simply telling boat builders to refer to that principle in order to determine whether an object will float.<sup>65</sup>

Thus, there must be “additional elements [to] transform the nature of the claim into a patent-eligible application.”<sup>66</sup>

STS believes the method described by the ‘143 Patent is nothing more than an attempt to patent the naturally-occurring product of xylitol. STS contends that the ‘143 Patent simply describes xylitol and teaches an application of “‘well-understood, routine, conventional activity previously engaged in by researchers in the field . . . .’”<sup>67</sup> For instance, STS argues that the “saline nasal wash solution, the bottles for nasal administration, and protocols to accomplish these activities, were conventional, routine and widely available in the art at the time the provisional patent application was filed.”<sup>68</sup>

Xlear disagrees, arguing that the method described in the ‘143 Patent provides “a way for xylitol/xylose to be more efficiently introduced to the nasopharynx through nasal administration, reducing bacteria in that area and subsequently reducing the occurrence of infections associated with those bacteria.”<sup>69</sup> Xylitol/xylose “had never previously been applied in this manner prior to the filing date of the ‘143 patent and was therefore an unconventional method.”<sup>70</sup> That is why the USPTO granted the patent, according to Xlear—because it was a *new application* of

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<sup>65</sup> *Id.*

<sup>66</sup> *Alice Corp.*, 134 S.Ct. at 2355.

<sup>67</sup> Defendant STS Health, LLC’s Reply Brief to Plaintiff’s Memorandum in Opposition to Defendant’s Motion to Dismiss the First Amended Complaint under Fed. R. Civ. P. 12(b)(6) (“Reply”) at 6, [docket no. 33](#), filed June 16, 2015 (quoting *Mayo*, 132 S.Ct. at 1294).

<sup>68</sup> Reply at 6.

<sup>69</sup> Opposition at 9.

<sup>70</sup> *Id.*

xylitol/xylose.<sup>71</sup> If this is true, and the ‘143 Patent embodies a new or novel application of xylitol, STS is incorrect that the ‘143 Patent is invalid.

This is a very close call. While STS asserts that saline nasal wash solution and the spray bottles used by Xlear to administer the solution may not be unique,<sup>72</sup> the record is not sufficient to conclusively establish that the “claims at issue are simply directed to a known natural sugar, xylitol, in known pre-existing nasal solutions, and administered via a conventional nasal spray” as STS argues.<sup>73</sup> Evidence is needed to know if the nasal solutions were in fact pre-existing or if there were any similar applications of xylitol prior to the ‘143 Patent that render the ‘143 Patent non-novel. At this stage, all of Xlear’s factual allegations that the ‘143 Patent claims a novel application of xylitol<sup>74</sup> must be accepted as true. The novelty of the ‘143 Patent is a factual allegation because it depends on whether other applications of xylitol existed at the time the ‘143 Patent that were similar to the ‘143 Patent.

Taking Xlear’s factual allegations as true, Claim 1 of the ‘143 Patent is eligible patent subject matter under § 101. It claims a *process* or *method* which is not a law of nature or natural phenomenon and which, according to Xlear, has not been previously applied in this manner. Thus, STS’s argument that the ‘143 Patent is invalid under 35 U.S.C. § 101 because it is directed to patent-ineligible subject matter is incorrect and the Motion on these grounds is denied.

**STS Does Not Establish that the ‘143 Patent Is Invalid under 35 U.S.C. § 112 ¶ 1**

Second, STS argues that the ‘143 Patent is invalid under 35 U.S.C. § 112 ¶ 1.<sup>75</sup> STS argues that paragraph 1 of § 112 requires that to be valid, a later-filed non-provisional

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<sup>71</sup> *Id.*

<sup>72</sup> Motion at 9.

<sup>73</sup> *Id.* at 10.

<sup>74</sup> *See* Complaint ¶¶ 8-11.

<sup>75</sup> Motion at 13.

application to be supported by an earlier provisional application.<sup>76</sup> STS argues that the claims of the ‘143 Patent must be, but are not, supported by the ‘184 provisional application filed on March 24, 1998. “For example,” STS argues, “the ‘143 patent claims are directed to a method of cleaning the nasopharynx – yet the ‘184 provisional application fails to set forth any such method, and never uses the term ‘cleaning.’”<sup>77</sup> Xlear, on the other hand, argues that determinations under § 112 are questions of fact and should not be decided at this stage.<sup>78</sup> Xlear correctly notes that questions of fact may not be decided on a motion to dismiss, because the plaintiff’s allegations must be accepted as true.<sup>79</sup> Xlear asserts that the allegations in its Complaint show that “the provisional application upon which the ‘143 Patent is based discloses that Dr. Jones’ invention includes a ‘beneficial washing effect.’”<sup>80</sup> This allegation, according to Xlear, precludes granting the motion to dismiss.<sup>81</sup> Xlear is correct.

STS accurately states that to receive the earlier priority date a later-filed patent application must be supported by an earlier application: “It is elementary patent law that a patent application is entitled to the benefit of the filing date of an earlier filed application only if the disclosure of the earlier application provides support for the claims of the later application, as required by [35 U.S.C. § 112](#).”<sup>82</sup> However, STS has not shown that, taking Xlear’s allegations as true, the ‘184 provisional application fails to support the ‘143 Patent. According to the Complaint’s allegations, the ‘184 provisional application “discloses, among other things, a preparation prepared by mixing xylitol with a saline solution that is effective for reducing the

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<sup>76</sup> *Id.* at 14.

<sup>77</sup> *Id.*

<sup>78</sup> Opposition at 11.

<sup>79</sup> *Id.* at 11-12.

<sup>80</sup> *Id.* at 13-14.

<sup>81</sup> *Id.* at 14.

<sup>82</sup> *In re Chu*, 66 F.3d 292, 297 (Fed. Cir. 1995).

incidence of upper respiratory infection in those at risk for recurrent infections and includes a beneficial washing effect.”<sup>83</sup> This allegation, accepted as true, contradicts STS’s assertion that the ‘184 provisional application does not refer to “cleaning.”<sup>84</sup> The parties certainly disagree about whether “washing” is the same as “cleaning,” but the Complaint’s factual allegations must be accepted as true. Therefore, for purposes of this motion, the ‘184 provisional application discloses washing. “Washing” is adequately similar to “cleaning”<sup>85</sup> as described in Claim 1 of the ‘143 Patent to determine that there is a sufficient written description in the ‘184 provisional application to support Claim 1 of the ‘143 Patent. Accordingly, STS’s motion is denied with respect to its § 112 ¶ 1 argument.

**STS Does Not Establish that the ‘143 Patent Is Invalid under 35 U.S.C. § 112 ¶ 2**

Next, STS argues that the ‘143 Patent is invalid under 35 U.S.C. § 112 ¶ 2.<sup>86</sup> STS argues that the claims of the ‘143 Patent are indefinite and invalid as a matter of law, and this legal determination can be made at the motion to dismiss stage.<sup>87</sup> STS argues that since claim construction generally involves looking at “intrinsic evidence of record (i.e., the patent itself) including the claims, the specification, and the prosecution history[.]” there is no need to wait for actual claim construction to construe the meaning of the claims and conclude they are invalid.<sup>88</sup> Xlear disagrees, and argues that STS has again raised an argument that is inappropriate at this state of the record. Xlear argues that there has been no claim construction, and no evidence from

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<sup>83</sup> Complaint ¶ 12.

<sup>84</sup> Motion at 14.

<sup>85</sup> “Wash” means “[t]o cleanse by means of water” or “[t]o cleanse, remove the dirt from (something) by affusion of or immersion in water,” while “clean” means “[t]o make clean” or “[t]o free from dirt, filth, or impurity.” “Wash” and “Clean,” Oxford English Dictionary Online (2015).

<sup>86</sup> Motion at 15.

<sup>87</sup> *Id.* at 15-16.

<sup>88</sup> *Id.* at 16.

one who is skilled in the art. Therefore, according to Xlear, we cannot now decide whether one of skill in the art could determine what an “effective amount” of xylitol in solution would be needed to adequately clean a human’s nasopharynx.<sup>89</sup> Xlear is correct.

35 U.S.C. § 112 ¶ 2 provides that a patent specification must “conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.”<sup>90</sup> STS cites *Atmel Corp. v. Information Storage Devices, Inc.*<sup>91</sup> and *BJ Services Co. v. Halliburton Energy Services, Inc.*<sup>92</sup> for the proposition that indefiniteness is a matter of law and should be decided by the court.<sup>93</sup> While STS is correct that indefiniteness is a matter of law, neither of the cases cited by STS establish that indefiniteness is decided at the motion to dismiss stage. Rather, *Atmel* was a case decided on summary judgment and *BJ Services* went to a jury. The other cases referred to by STS are similarly decided at later stages of a case.<sup>94</sup> Thus, none of the cases cited by STS establish that indefiniteness may be determined on a motion to dismiss.

Further, STS has not shown that the ‘143 Patent is not specific enough under 35 U.S.C. § 112 ¶ 2. In opposing STS’s arguments, Xlear cites to *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*,<sup>95</sup> which noted that “‘effective amount’ is a common and generally acceptable term for pharmaceutical claims and is not ambiguous or indefinite, provided that a person of ordinary skill in the art could determine the specific amounts without undue

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<sup>89</sup> Opposition at 14.

<sup>90</sup> 35 U.S.C. § 112(b).

<sup>91</sup> 198 F.3d 1374, 1378 (Fed. Cir. 1999).

<sup>92</sup> 338 F.3d 1368, 1372 (Fed. Cir. 2003).

<sup>93</sup> Motion at 15-16.

<sup>94</sup> *Id.* at 16 (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) and *In re Fredericksen*, 213 F.2d 547 (C.C.P.A. 1954).

<sup>95</sup> *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir. 2003).

experimentation.”<sup>96</sup> As *Geneva* points out, to show indefiniteness, a party must show that a person of ordinary skill in the art could not determine what an “effective amount” is without “undue experimentation.”<sup>97</sup> Xlear is correct that without evidence from one who is skilled in the art, this determination cannot be made. Thus, this is not the appropriate stage of litigation to conclude whether Claim 1 is indefinite. Accordingly, STS’s motion to dismiss is denied on § 112 ¶ 2 grounds.

**STS Does Not Establish that the ‘143 Patent Is Invalid under 35 U.S.C. § 102(e)**

Finally, STS argues that the ‘143 Patent is invalid as being anticipated under 35 U.S.C. § 102(e).<sup>98</sup> 35 U.S.C. § 102(e) provides that:

a person shall be entitled to a patent unless an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent . . . or a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent.<sup>99</sup>

STS argues that the ‘143 Patent “seeks priority to the March 28, 1998 ‘184 provisional application, but such provisional application does not support the claims of the ‘143 patent.”<sup>100</sup> Specifically, STS argues that “the asserted claims of the ‘143 patent are not entitled to the effective filing date (March 28, 1998) of the ‘184 provisional application because such claims are directed to subject matter that was not disclosed in the four-page ‘184 provisional application.”<sup>101</sup> Instead, STS argues, support for the ‘143 claims is found in the “more robust 21-page, provisional application No. 60/106,388 filed on October 30, 1998 (which matured into the

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<sup>96</sup> *Id.* at 1383-83.

<sup>97</sup> *Id.*

<sup>98</sup> Motion at 19.

<sup>99</sup> 35 U.S.C. § 102(e).

<sup>100</sup> Motion at 19.

<sup>101</sup> *Id.* at 20.



‘883 patent).’<sup>102</sup> Therefore, STS contends, Xlear cannot claim March 28, 1998 as the priority date because the claims found in the ‘143 Patent “are limited to the filing date of the regular ‘143 patent, *i.e.*, December 23, 1998” and are therefore “anticipated by the ‘883 patent, which enjoys an earlier priority date of October 30, 1998, and discloses the claimed subject matter of the ‘143 patent.”<sup>103</sup> STS’s argument depends heavily on its assertion that “[t]here is no support in the ‘184 provisional application filed March 24, 1998 for the claims of the ‘143 patent.”<sup>104</sup> But this argument has already been addressed above. The ‘184 provisional application discusses the “beneficial washing effect” of the claimed invention, and states that the invention’s purpose is to “treat respiratory infections” by administering the xylitol/saline product through the nostrils.<sup>105</sup> This shows support for the ‘143 Patent claims.

Furthermore, as Xlear correctly notes, “[i]nvalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference.”<sup>106</sup> Whether all of the elements and limitations of the ‘143 Patent are found within an earlier reference is dependent on “question[s] of fact”<sup>107</sup> that cannot be decided on a motion to dismiss. Accordingly, STS’s motion to dismiss is denied on § 102(e) grounds also.

### **NEW ARGUMENTS RAISED IN REPLY ARE REJECTED**

STS raises new arguments in its Reply that were not mentioned in its Motion. For instance, STS argues that Xlear’s Complaint makes conclusory allegations and does not state a

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<sup>102</sup> *Id.*

<sup>103</sup> *Id.*

<sup>104</sup> *Id.* at 21.

<sup>105</sup> ‘184 Provisional Application, Exhibit D to Motion, [docket no. 30-4](#), filed April 13, 2015.

<sup>106</sup> Opposition at 15 (quoting *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991)).

<sup>107</sup> See Opposition at 15 (quoting *Glaverbel Socete Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 1554 (Fed. Cir. 1995) (“Anticipation is a question of fact.”)).

plausible claim for relief.<sup>108</sup> STS also argues that Xlear failed to give STS prior notice of alleged infringement before filing suit, which violates Form 18.<sup>109</sup> STS also argues that it is “not a human and does not have a nasopharynx,” and therefore it “cannot directly infringe the method claimed in the ‘143 Patent.”<sup>110</sup> These arguments were not briefed in the Motion, Xlear has not had an opportunity to address them, and will not be addressed here.<sup>111</sup>

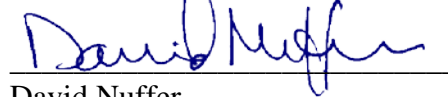
### CONCLUSION AND ORDER

Because STS has failed to show that the ‘143 Patent is invalid under [35 U.S.C. §§ 101](#), 102, or 112,

IT IS HEREBY ORDERED that the Motion<sup>112</sup> is DENIED.

Dated December 14, 2015.

BY THE COURT:



David Nuffer  
United States District Judge

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<sup>108</sup> Reply at 1-2.

<sup>109</sup> *Id.* at 2-3.

<sup>110</sup> *Id.* at 4.

<sup>111</sup> DUCivR 7-1(b)(2)(A) (“Reply memoranda . . . must be limited to rebuttal of matters raised in the memorandum opposing the motion.”).

<sup>112</sup> Defendant STS Health, LLC’s Motion to Dismiss Plaintiff Xlear, Inc.’s First Amended Complaint under [Fed. R. Civ. P. 12\(b\)\(6\)](#) and Memorandum in Support (“Motion”), [docket no. 29](#), filed April 13, 2015.